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TITLE: GWOT Vascular Injury Study 2 Supplemental Project: Impact of Prophylactic Fasciotomy

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14. ABSTRACT

The majority of battlefield injures involve the extremities and encompasses either isolated or a combination of vascular injury, penetrating trauma, crush, blunt trauma, burns, and fractures. Each of these injuries places the wounded Service members at risk for developing acute extremity compartment syndrome (ACS). Under far forward surgical conditions the policy is to manage these at-risk patients with prophylactic fasciotomies. The objective of this study is to determine the impact of the widespread use of fasciotomies on a mortality, delayed amputation, fasciotomy related morbidities, and fasciotomy wound management.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Introduction:

This is a retrospective analysis of a cohort of US service members included in the wartime vascular injury database. Information regarding service members with a lower extremity vascular injury will be used to determine fasciotomy rates, wound management, and iatrogenic complications. The impact of injury and fasciotomy on the service members' return-to-duty and long-term disability will also be examined.

Keywords:

Vascular Injury
Compartment Syndrome
Extremity
Fasciotomy

ACCOMPLISHMENTS:.

- IRB protocol continuing approval approved by MRMC IRB (June 2016).
- Additional staff to review charts hired (March 2016).
- 56.8% (483/851) of all charts in the database reviewed.
- CY 2005, 2006, 2010 & 2011 chart reviews have all been completed.
- Completed data has been sent to our statistician to for preliminary data analysis

What were the major goals of the project?

The overall goal is to determine the impact of the widespread use of fasciotomies on current medical/surgical practices, management guidelines, medical needs, as well as future research direction. The specific aims are:

- Aim 1. Characterization of patients-demographics, injury, fasciotomy.
- Aim 2. Characterize the morbidities associated with fasciotomy.
- Aim 3. Determine the impact of fasciotomy on delayed amputation rate.
- Aim 4. Characterize fasciotomy wound management.

Currently 56.8% of all charts in the database have been reviewed. Therefore, no characterization or analysis of data has started.

What was accomplished under these goals?

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The main focus of this past year has been chart reviews of data collection for patients included in the database. Currently 56.8% of all charts in the database have been reviewed. Therefore no characterization or analysis of data has started. Details of the injury severity and demographics of the completed years to date are contained in Appendix 1 and Appendix 2.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period chart reviews and data analysis will continue.

Impact

As chart reviews to obtain data are not completed, there has not been enough data collected to change practice or behaviors.

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

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Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

Changes/Problems

A No Cost Extension request has been submitted.

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

PRODUCTS:

Nothing to report

Publications, conference papers, and presentations

Nothing to report

Journal publications.
Nothing to report

Books or other non-periodical, one-time publications.
Nothing to report

Other publications, conference papers, and presentations.

Nothing to report

Website(s) or other Internet site(s)
Nothing to report

Technologies or techniques
Nothing to report

Inventions, patent applications, and/or licenses
Nothing to report

Other Products
Nothing to report

Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name:	Thomas Walters
Project Role:	PI
Nearest person month worked:	2.4
Contribution to Project:	Dr. Walters is a research physiologist and a member of the Extremity Trauma and Regenerative Medicine Task area at the U.S Army Institute of Surgical Research, San Antonio, TX. He is directs the muscle trauma research laboratory and has expertise in animal and human research. His research focus is on the treatment and detection of acute compartment syndrome and related issues involving combat related muscle trauma. He is experienced in conducting retrospective studies involving battlefield extremity trauma from the wars in Iraq and Afghanistan. He is the co-chair of Combat Casualty Care Research Program Integrated Product Team tasked with identifying alternatives to fasciotomy. Dr. Walter's provides the necessary scientific leadership, administrative oversight, and support for all aspects of the study, and ensure personnel and departmental resources are properly aligned to achieve the scope of work.
Name:	Diane Miller
Project Role:	Program Manager
Nearest person month worked:	12
Contribution to Project:	Ms. Miller is responsible for the day-to-day operations of the study. She will be responsible for assisting compilation of radiographic images and may assist with chart abstraction. She will also assist with the preparation of all study related correspondence and technical reports, maintain research files and data, procure study supplies and coordinate all procurement requests through The Geneva Foundation, and ensure budgetary adherence.
Name:	Leslie DuBios
Project Role:	Research Nurse
Nearest person month worked:	12
Contribution to Project:	Ms. DuBois's role involves data collection and management of patient records and source documents for the wartime vascular injury study. Extracting patient

	information from the GWOTVII database, patient records, and other sources. She is responsible for working with a multidisciplinary research teams which entails the principal investigator, assistant investigators, other research nurse coordinators, residents, program manager, and statisticians. Duties include submitting study protocol revisions and amendments to the Institutional Review Board (IRB) for approval, coordinating with the IRB to ensure safety, regulatory and ethical compliance and protection of the study subjects.
Name:	Julie Cutright
Project Role:	Research Nurse
Nearest person month worked:	12
Contribution to Project:	Ms. Cutright's role involves data collection and management of patient records and source documents for the wartime vascular injury study. Extracting patient information from the GWOTVII database, patient records, and other sources. She is responsible for working with a multidisciplinary research teams which entails the principal investigator, assistant investigators, other research nurse coordinators, residents, program manager, and statisticians. Duties include submitting study protocol revisions and amendments to the Institutional Review Board (IRB) for approval, coordinating with the IRB to ensure safety, regulatory and ethical compliance and protection of the study subjects.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission.
Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

What other organizations were involved as partners?

N/A

Special Reporting Requirements

Quad Chart: The Quad Chart (available on https://www.usamraa.army.mil) shall be updated and submitted as an appendix.

Appendix 1: Demographic Data for 2005 & 2006 and 2010 & 2011

Age at time of Injury	Fasciotomy		No Fasciotomy	
2005 & 2006				
2005 & 2006 Average	26.1		24.1	
2005 & 2006 Range	19-49		19-40	
2010 & 2011				
2010 & 2011 Average	25.3		25.1	
2010 & 2011 Range	19-41.3		19-42	
Overall				
Overall AVG	25.8		24.6	
Overall RANGE	19-49		19-42	

Gender	Fasciotomy		No Fasciotomy	
2005 & 2006				
Male	98		38	
Female	0		0	
2010 & 2011				
Male	59		36	
Female	0		0	
Branch of Service	Fasciotomy		No Fasciotomy	
2005 & 2006				
Army	65	66.3%	27	71.1%
Navy	3	3.1%	0	0.0%
Air Force	0	0.0%	1	2.6%
Marines	30	10.0%	10	26.3%
2010 & 2011				
Army	31	52.5%	21	58.3%
Navy	1	1.7%	0	0.0%
Air Force	3	5.1%	0	0.0%
Marines	24	40.7%	15	41.7%
Overall				
Army	96	61.1%	48	64.9%
Navy	4	2.5%	0	0.0%
Air Force	3	1.9%	1	1.4%
Marines	54	34.4%	25	33.8%
Method of Injury	Fasciotomy		No Fasciotomy	
2005 & 2006				
Blast (penetrating)	51	52.0%	25	65.8%
Blast (0ther/NOS)	14	14.3%	3	7.9%
Penetrating (non-blast)	31	31.6%	9	23.7%
Blunt/Crush	2	10.0%	1	2.6%
2010 & 2011				
Blast (penetrating)	22	37.3%	17	47.2%
Blast (0ther/NOS)	9	15.3%	5	13.9%
Penetrating (non-blast)	26	44.1%	14	38.9%
Blunt/Crush	2	3.4%	0	0.0%
Overall				
Blast (penetrating)	73	46.5%	42	56.8%
Blast (0ther/NOS)	23	14.6%	8	10.8%
Penetrating (non-blast)	57	36.3%	23	31.1%
Blunt/Crush	4	2.5%	1	1.4%
Years on Active Duty post injury[4]	Fasciotomy		No Fasciotomy	
2005 & 2006 Injury				
Still AD	12	12.2%	5	13.2%
Deceased	3	3.1%	1	2.6%

Unknown	14	14.3%	7	18.4%
Separated/Retired	69	70.4%	25	65.8%
Average years to separation	2.9		1.9	
Range	0.5-8.8		0.7-4.9	
2010 & 2011				
Still AD	10	16.9%	6	16.7%
Deceased	2	3.4%	3	8.3%
Unknown	0	0.0%	0	0.0%
Separated/Retired	47	79.7%	27	75.0%
Average years to separation	2.2		1.9	
Range	0.9-3.4		0.4-2.9	
Overall				
Still AD	22	14.0%	11	14.9%
Deceased	5	3.2%	4	5.4%
Unknown	14	8.9%	7	9.5%
Separated/Retired	116	73.9%	52	70.3%
Overall AVG	2.6		1.9	
Overall RANGE	0.5-8.8		0.4-4.9	

Days initial inpatient post injury	Fasciotomy		No Fasciotomy	
2005&2006				
Deceased	2	2.0%	1	2.6%
Unknown	1	1.0%	0	0.0%
Discharged Alive	95	96.9%	37	97.4%
Average days to discharge	49.6		38.1	
Range	3.6-396		3.9-202	
2010 & 2011				
Deceased	2	3.4%	2	5.6%
Unknown	0	0.0%	0	0.0%
Discharged Alive	57	96.6%	34	94.4%
Average days to discharge	46.5		37	
Range	8.8-412		5-167	
Overall				
Deceased	4	2.5%	3	4.1%
Unknown	1	0.6%	0	0.0%
Discharged Alive	152	96.8%	71	95.9%
Overall AVG	48.4		37.6	
Overall RANGE	3.6-412		3.9-202	
Rank at time of injury	Fasciotomy		No Fasciotomy	
2005 & 2006				
E1-E4	56	57.1%	25	65.8%
E5-Warant Officer	36	36.7%	12	31.6%
Officer	6	6.1%	1	2.6%
2010 & 2011				
E1-E4	42	71.2%	24	66.7%
E5-Warant Officer	12	20.3%	12	33.3%
Officer	5	8.5%	0	0.0%
Overall				
E1-E4	98	62.4%	49	66.2%
E5-Warant Officer	48	30.6%	24	32.4%
Officer	11	7.0%	1	1.4%
Documented Complications[4-7]	Fasciotomy		No Fasciotomy	
2005 & 2006				
Non-Vascular Extremity Complication	82	83.7%	19	50.0%
Non-Vascular non-extremity Complication	9	9.2%	2	5.3%
Extremity Vascular Complication	30	30.6%	5	13.2%
No documented complications	15	15.3%	18	47.4
2010 & 2011				
Non-Vascular Extremity Complication	43	72.9%	18	50.0%
Non-Vascular non-extremity Complication	17	28.8%	5	13.9%
Extremity Vascular Complication	20	33.9%	13	36.1%
No documented complications	11	18.6%	16	44.4%

Overall				
Non-Vascular Extremity Complication	125	79.6%	37	50.0%
Non-Vascular non-extremity Complication	26	16.6%	7	9.5%
Extremity Vascular Complication	50	31.8%	18	24.3%
No documented complications	26	16.6%	34	45.9%

Appendix 2: Injury Severity Data for 2005 & 2006 and 2010 & 2011

Year of Injury	Fasciotomy		No Fasciotomy	
2005 & 2006	**98**		**38**	
2010 & 2011	**59**		**36**	
TOTAL	**157**	**68.0%**	**74**	**32.0%**
Injury Severity Score 2005 [1]	Fasciotomy		No Fasciotomy	
2005 & 2006				
2005 & 2006 Average	15.56		15.3	
2005 & 2006 Range	2-50		5-43	
2010 & 2011				
2010 & 2011 Average	16.4		18.5	
2010 & 2011 Range	5-43		4-57	
Overall				
Overall AVG	**15.9**		**16.8**	
Overall RANGE	**2-50**		**19-42**	
AIS Extremity (Body Region 5) [2]	Fasciotomy		No Fasciotomy	
2005 & 2006				
Vascular (total number)	**98**	**100%**	**38**	**100%**
2005 & 2006 Average	2.76		2.45	
2005 & 2006 Range	1-4		1-4	
Nerve (total number)	**52**	**53%**	**14**	**37%**
2005 & 2006 Average	2.11		2.00	
2005 & 2006 Range	2-3		2-2	
Ortho (total number)	**55**	**56%**	**15**	**39%**
2005 & 2006 Average	2.78		2.73	
2005 & 2006 Range	2-3		2-3	
Soft Tissue/other (total number)	**26**	**27%**	**12**	**32%**
2005 & 2006 Average	1.77		1.75	
2005 & 2006 Range	1-3		1-3	
2010 & 2011				
Vascular (total number)	**59**	**100%**	**36**	**100%**
2010 & 2010 Average	2.8		2.94	
2010 & 2010 Range	1-4		1-4	
Nerve (total number)	**37**	**63%**	**18**	**50%**
2005 & 2006 Average	2.11		2.06	
2005 & 2006 Range	2-3		2-3	
Ortho (total number)	**39**	**66%**	**12**	**33%**
2005 & 2006 Average	2.69		2.83	
2005 & 2006 Range	2-3		2-3	
Soft Tissue/other (total number)	**9**	**15%**	**15**	**42%**
2005 & 2006 Average	1.67		2.00	
2005 & 2006 Range	1-3		1-3	

Overall				
Vascular (total number)	**157**	**100%**	**74**	**100%**
Overall Average	2.77		2.69	
Overall Range	1-4		1-4	
Nerve (total number)	**89**	**57%**	**32**	**43%**
Overall Average	2.11		2.03	
Overall Range	2-3		2-3	
Ortho (total number)	**94**	**60%**	**27**	**36%**
Overall Average	2.74		2.78	
Overall Range	2-3		2-3	
Soft Tissue/other (total number)	**35**	**22%**	**27**	**36%**
Overall Average	1.74		1.89	
Overall Range	1-3		1-3	
Mangled Extremity Severity Score (MESS)[3]	Fasciotomy		No Fasciotomy	
2005 & 2006				
2005 & 2006 Average	5.85		5.26	
2005 & 2006 Range	2-9		2-9	
MESS >7 (total #)	**12**	**12%**	**2**	**5%**
2005 & 2006 Average	8.33		9.00	
2005 & 2006 Range	8-9		9-9	
2010 & 2011				
2010 & 2010 Average	5.05		5.13	
2010 & 2010 Range	3-8		3-9	
MESS >7 (total #)	**3**	**5%**	**3**	**8%**
2010 & 2010 Average	8		9.00	
2010 & 2010 Range	8-8		9-9	
Overall				
Overall Average	5.68		5.20	
Overall Range	2-9		2-9	
MESS >7 (total #)	**15**	**10%**	**5**	**7%**
Overall Average	8.27		9.00	
Overall Range	8-9		9-9	

[1]Injury Severity Score 2005: The Injury Severity Score (ISS) is an anatomical scoring system that provides an overall score for patients with multiple injuries. Each injury is assigned an Abbreviated Injury Scale (AIS) score and is allocated to one of six body regions (Head, Face, Chest, Abdomen, Extremities (including Pelvis), and External). Only the highest AIS score in each body region is used. The 3 most severely injured body regions have their score squared and added together to produce the ISS score. http://www.trauma.org/archive/scores/iss.html

[2]Abbreviated Injury Score (Affected Extremity): The Abbreviated Injury Scale (AIS) is an anatomical scoring system first introduced in 1969. Injuries are ranked on a scale of 1 to 6, with 1 being minor, 5 severe and 6 un- survivable injuries. This represents the 'threat to life' associated with an injury and is not meant to represent a comprehensive measure of severity. The AIS is not an injury scale, in that the difference between AIS1 and AIS2 is not the same as that between AIS4 and AIS5. For the purposes of this study, AIS Body Region 5 is further recorded as worst/most severe vascular, orthopedic/bone, nerve, or other injury. http://www.trauma.org/index.php/main/article/510/

[3] Mangled Extremity Severity Score: The most widely used lower-limb-salvage scoring system, used to help clinicians decide whether to try and save a leg or perform early amputation, which is based on assessment of combined vascular and orthopedic injuries. http://medical-dictionary.thefreedictionary.com/Mangled+Extremity+Severity+Score

[4] All data collection stops at either the last day of Active Duty, or 12/1/2014 – whichever comes first. Therefore, the length of time on Active Duty Post injury is potentially greater for those injured earlier. Also the number of documented complications is potentially higher for those injured earlier, as they will have more documentation in military health care records.

[5] Non-Vascular Extremity Complications indicates service member had a documented diagnosis or treatment for one or more of the following: Infection, tethering, contracture, foot drop, motor dysfunction, muscle excision (after level 3 care), loss of compartment, herniation, loss of sensation, and/or limb swelling.

[6]Non-Vascular Non-Extremity Complications indicates service member had a documented diagnosis or treatment for one or more of the following: Rhabdomyolysis, Renal Failure, Paralysis, or Pulmonary Embolism

[7]Extremity VASCULAR Complications indicate service member had a documented diagnosis or treatment for one or more of the following: DVT, Thrombosis, Aneurysm, Pseudo-aneurysm, vascular blow-out, stenosis, failed vascular repair, AV fistula, and/or venous insufficiency.

GWOT Vascular Injury Study 2 Supplemental Project: Impact of Prophylactic Fasciotomy

BAA Log Number 13180003

W81XWH-14-2-0165

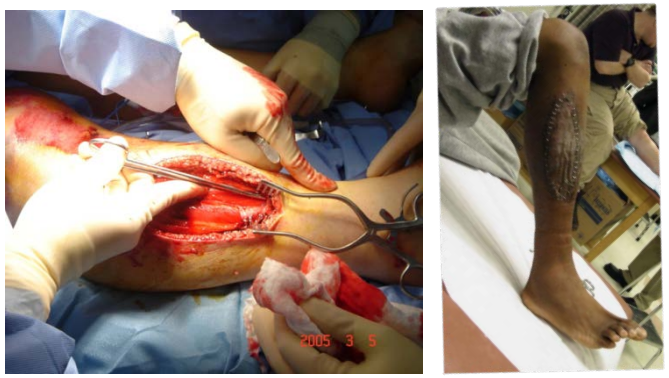
PI: Thomas J. Walters, Ph.D. **Org:** USAISR/The Geneva Foundation **Award Amount:** $791,101

Study/Product Aim(s)

- Specific Aim 1: Identify patients that received fasciotomies and characterize the data relating to demographics, mortality, primary injury, complications, return-to-duty, and long-term disabilities.
- Specific Aim 2: Determine the incidence of morbidities associated with fasciotomy; 3) Assess the impact of fasciotomy on delayed amputation; and 4) Characterize fasciotomy wound management.

Approach

This study will involve a retrospective analysis of a cohort of US service members included in the GWOTVII database. Information regarding fasciotomy wound management and iatrogenic complications of fasciotomy will be obtained from individual patient records. Information specific for return-to-duty and long-term disability will be obtained from the Physical Evaluation Board Liaison Office for each branch of service.



(Left) Fasciotomy of the anterior compartment of the lower leg. (Right) The need to close fasciotomy wound with skin graft suggests that muscle swelling was sufficient to induce compartment syndrome. This project will examine the complications and morbidities associated with fasciotomy wounds.

Timeline and Cost

Activities	Year 01	Year 02	Year 03
Obtain IRB/HRPO approval, Hire Staff and FaVIO database development			
Extract data from GWOTVII database			
Conduct Chart Reviews			
Data Analysis and Reporting			
Estimated Budget ($791K)			

Updated: 25 OCT 2016

Goals/Milestones

CY14 Goal – Protocol /Staffing

☑ Write and submit protocol to IRB

☑ Hire project manager

CY15 Goals – Data Collection

☑ Obtain IRB and HRPO approval

☑ Extract data/Conduct chart reviews

☑ Complete staff hiring

CY16 Goals – Data Collection/Analysis

☑ Conduct chart reviews

☑ Request No Cost Extension

CY17 Goals

❑ Complete chart reviews

❑ Analyze data/Submit results for publication

Comments/Challenges/Issues/Concerns

- Currently 3 staff reviewing charts. 56.8% of 851 records reviewed.
- **Budget Expenditure as f 9.30.16**

Projected Expenditure:$791,101

Actual Expenditure: $429,630